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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/424,431	03/16/2000	JOHN W WONG	287300022USA	7974	
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09/424,431 03/16/2000		EXAMINER			
		MENDOZA, MICHAEL G			
BLOOMFIELD	HILLS, MI 48303		ART UNIT	PAPER NUMBER	
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			DATE MAILED: 03/26/2002	DATE MAILED: 03/26/2002	

Please find below and/or attached an Office communication concerning this application or proceeding.



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Office Action Summary		Application No.	Applicant(s)
		09/424,431	WONG, JOHN W
		Examiner	Art Unit
		Michael G. Mendoza	3761
Period fo	The MAILING DATE of this communication ap	ppears on the cover sheet wi	th the correspondence address
A SH THE - Exte after - If the - If NC - Failu - Any	ORTENED STATUTORY PERIOD FOR REP MAILING DATE OF THIS COMMUNICATION ensions of time may be available under the provisions of 37 CFR 1 SIX (6) MONTHS from the mailing date of this communication. It is period for reply specified above is less than thirty (30) days, a represent of the provision of the provisions of the provision	. 1.136(a). In no event, however, may a resply within the statutory minimum of thirty d will apply and will expire SIX (6) MON the cause the application to become AB.	eply be timely filed  y (30) days will be considered timely.  THS from the mailing date of this communication.
1)⊠	Responsive to communication(s) filed on 16	March 2000 .	
2a) <u></u> □		his action is non-final.	
3)[]	Since this application is in condition for allow closed in accordance with the practice under the condition of Claims	vance except for formal mat	ters, prosecution as to the merits is 0. 11, 453 O.G. 213.
·			
	Claim(s) <u>1-20</u> is/are pending in the application		
	4a) Of the above claim(s) is/are withdra	awn from consideration.	
	Claim(s) is/are allowed. Claim(s) <u>1-20</u> is/are rejected.		
	Claim(s) is/are objected to.		•
Applicati	Claim(s) are subject to restriction and/o on Papers		
	The specification is objected to by the Examine		
10) 🔲 ¯	The drawing(s) filed on is/are: a)□ acce		•
	Applicant may not request that any objection to the		
11)[_] 7	The proposed drawing correction filed on		sapproved by the Examiner.
40)	If approved, corrected drawings are required in re		
	The oath or declaration is objected to by the Ex	xaminer.	
	nder 35 U.S.C. §§ 119 and 120		
	Acknowledgment is made of a claim for foreig	n priority under 35 U.S.C. §	119(a)-(d) or (f).
	☐ All b)☐ Some * c)☐ None of:		
	1. Certified copies of the priority document		
	2. Certified copies of the priority document	•	
	<ol> <li>Copies of the certified copies of the prio application from the International Buse the attached detailed Office action for a list</li> </ol>	reau (PCT Rule 17.2(a)).	_
	cknowledgment is made of a claim for domesti		
	☐ The translation of the foreign language pro	The state of the s	
15)∏ A	cknowledgment is made of a claim for domest	tic priority under 35 U.S.C. §	§ 120 and/or 121.
\ttachment(		•	-
) 🔲 Notice	of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO-948) ation Disclosure Statement(s) (PTO-1449) Paper No(s) _	5) Notice of Inf	ormal Patent Application (PTO-152)

U.S. Patent and Trademark Office PTO-326 (Rev. 04-01)

#### **DETAILED ACTION**

# Specification

1. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

# Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 3. Claims 1, 2, 3, 4, 5, 6, 7, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Rienmueller et al. 5,067,494.
- 4. As to claim 1, Rienmueller et al. teaches a method for delivering radiation therapy to a patient during suspended ventilation, the method comprising the steps of: identifying a specific air flow direction and lung volume (col. 2, lines 3-4); suspending patient ventilation at a specific air flow direction and lung volume (col. 2, lines 12-19); and administering radiation therapy during the suspension of patient ventilation (col.1, lines 63-65).
- 5. As to claim 2, Rienmueller et al. teaches a method for delivering radiation therapy to a patient during suspended ventilation according to claim 1, the method including the step of attaching a respiration monitor 6 to the patient through a mouth piece 9 that includes one or more air flow valves 14.

- 6. As to claim 3, Rienmueller et al. teaches a method for delivering radiation therapy to a patient during suspended ventilation according to claim 1, the method including the step of utilizing a computer control to provide a measure of the cyclical expiration and inhalation cycle of the patient (col. 3, lines 14-16).
- 7. As to claim 4, Rienmueller et al. teaches a method for delivering radiation therapy to a patient during suspended ventilation according to claim 2, the method including the step of operating the one or more air flow valves of the mouth piece to suspend the patient's breathing at a desired point (col. 2, lines 12-19).
- 8. As to claim 5, Rienmueller et al. teaches a method for delivering radiation therapy to a patient during suspended ventilation according to claim 4, the method including the steps of halting inhalation and exhalation during the time of suspended breathing (col. 2, lines 12-19).
- 9. As to claim 6, Rienmueller et al. teaches a method for delivering radiation therapy to a patient during suspended ventilation according to claim 1, the method including repeating the stop of suspending patient ventilation at a specific air flow direction and lung volume as necessary to administer repeated radiation doses (col. 1, line 26-35).
- 10. As to claim 7, Rienmueller et al. teaches a method for delivering radiation therapy to a patient during suspended ventilation according to claim 1,the method including undertaking CT planning and treatment at a reproducible ventilatory phase (col. 1, lines 26-35).

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11. As to claim 9, Rienmueller et al. teaches a method for delivering radiation therapy to a patient during suspended ventilation according to claim 1, the method including the steps of acquiring CT scans at different respiratory phases (col. 1, lines 26-35).

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- 12. Claims 10, 11, 12, 13, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Rienmueller et al.
- 13. As to claim 10, Rienmueller et al. teaches a method for establishing breath-holding reproducibility in a patient for the delivery of radiation therapy, the method comprising the steps of: identifying a lung volume (col.2 lines 8-9); suspending patient ventilation at a lung volume (col. 2, lines 12-19); and administering radiation therapy during the suspension of patient ventilation (col.1, lines 63-65).
- 14. As to claim 11, Rienmueller et al. teaches a method for establishing breath-holding reproducibility in a patient for the delivery of radiation therapy according to claim 10, the method including the step of attaching a respiration monitor to the patient through a mouthpiece 9 that includes one or more air flow valves 14.
- 15. As to claim 12, Rienmueller et al. teaches a method for establishing breath-holding reproducibility in a patient for the delivery of radiation therapy according to claim 11, the method including the step of operating the one or more air flow valves of the mouthpiece to suspend the patient's breathing at a desired point (col. 2, lines 12-19).
- 16. As to claim 13, Rienmueller et al. teaches a method for establishing breathholding reproducibility in a patient for the delivery of radiation therapy according to claim

- 10, the method including the steps of halting inhalation and exhalation during the time of suspended breathing (col. 2, lines 12-19).
- 17. As to claim 14, Rienmueller et al. teaches a method for establishing breath-holding reproducibility in a patient for the delivery of radiation therapy according to claim 10, the method including repeating the step of suspending patient ventilation at a specific air flow direction and lung volume as necessary to administer repeated radiation doses (col. 1, line 26-35).
- 18. Claims 15, 16, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Rienmueller et al.
- 19. As to claim 15, Rienmueller et al. teaches an apparatus for suspending ventilation in a patient and delivering radiation therapy to the patient during suspended ventilation, the apparatus comprising: an apparatus for identifying a specific air flow direction and lung volume of the patient 8; an apparatus for suspending patient ventilation at a specific air flow direction and lung volume 14; and an apparatus for administering radiation therapy during the suspension of patient ventilation 1.
- 20. As to claim 16, Rienmueller et al. teaches an apparatus for suspending ventilation in a patient and delivering radiation therapy to the patient during suspended ventilation according to claim 15 wherein the apparatus for suspending patient ventilation includes a ventilator assembly having one or more selectively operable valves fig 2.
- 21. As to claim 20, Rienmueller et al. teaches an apparatus for suspending ventilation in a patient and delivering radiation therapy to the patient during suspended

ventilation according to claim 15, further including a mouth piece 9 attached to the ventilator assembly.

## Claim Rejections - 35 USC § 103

- 22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 23. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rienmueller et al. in view of Donaldson et al. 5,950,631
- 24. As to claim 8, Rienmueller et al. teaches the method for delivery radiation therapy to a patient during suspended ventilation according to claim 1. It should be noted that Rienmueller et al. fails to teach the step of applying to the patient a mechanical device for attachment to the patient's nose for temporarily halting air passage therethrough. However Donaldson et al. does teach the step of applying to the patient a mechanical device for attachment to the patient's nose 70 for temporarily halting air passage therethrough. Therefore it would have been obvious to one of ordinary skill in the art to modify the method of Rienmueller et al. to include the step of applying to the patient a mechanical device for attachment to the patient's nose to prevent breathing through the nose affecting treatment.
- 25. Claims 17, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rienmueller et al. in view of Beran 4,815,459.

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26. As to claim 17, Rienmueller et al. teaches an apparatus for suspending ventilation in a patient and delivering radiation therapy to the patient during suspended ventilation according to claim 15 wherein the ventilator assembly fig. 2includes a first one-way valve 14. It should be noted that Rienmueller et al. fails to teach a t-connector, a second one-way valve, and a pneumotach. However, Beran does teach a t-connector 12, a second one-way valve (col. 4, line 13), and a pneumotach 50. Therefore it would have been obvious to one of ordinary skill in the art to modify the apparatus of Rienmueller et al. to include the assembly of Beran to measure air pressure and flow rate of the patient.

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- 27. As to claim 18, the combination of Rienmueller/Beran teaches an apparatus for suspending ventilation in a patient and delivering radiation therapy to the patient during suspended ventilation according to claim 17 further including a computer 5 and 13, the first one-way valve, and the pneumotach being operably associated with the computer.
- 28. As to claim 19, the combination of Rienmueller/Beran teaches an apparatus for suspending ventilation in a patient and delivering radiation therapy to the patient during suspended ventilation according to claim 18 further including a monitor 6 for providing a readout of cyclical lung volume trace an target respiration level while the patient is breathing, the monitor being operably attached to the computer.

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### Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (703) 305-3285. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Weiss can be reached on (703) 308-2702. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communications and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

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MM March 19, 2002 John G. Weiss

Supervisory Patent Examiner

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Group 3700